Summary of Clinical Trial Results

A study to find out if people get the same amount of medicine (alectinib) – when they take different forms of the medicine – with or without food

See the end of the summary for the full title of the study.

About this summary

This is a summary of the results of a clinical trial (called a "study" in this document).

This summary is written for:

- Members of the public
- People who took part in the study

This summary is based on information known at the time of writing.

The study started in January 2021 and finished in March 2021. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

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- **Always speak to your doctor before making any decisions about your treatment.**

Contents of the summary

Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about caner and the medicine studied – "alectinib".

Key information about this study

- This study was done to find out if taking different forms of the same medicine resulted in getting the same amount of medicine in the body.
- People who participated in this study were given a medicine, called, "alectinib", in capsule form and in liquid suspension form. Both forms were taken by mouth.
- The effect of taking the medicine with and without food was also studied.
- This study included 28 healthy men and non-childbearing healthy women in one country.
- The main finding was that taking alectinib in liquid suspension form resulted in more exposure to the medicine in the body in comparison to the same dose taken in capsule form.
- Taking the medicine with food increased the amount of medicine in the body.
- There were no serious side effects caused by the medicine in this study.

1. General information about this study

Why was this study done?

"ALK" is a type of protein – an "enzyme" that carries out reactions in the cell. In some people, a change can come about in the DNA - in the *ALK* gene. As a result, these people start making a different form of ALK protein called "ALK fusion protein".

While ALK protein can turn on and off normally, ALK fusion protein is always on ("constitutively active") – it does not turn off. This level of activity can lead to uncontrolled cell growth and cancer.

"Alectinib" is a medicine that works by stopping the activity of ALK fusion protein. This medicine can be effective for cancers that have the ALK fusion protein present.

Alectinib has been tested in several clinical trials. It has been approved for adult patients with lung cancer where ALK fusion protein is present. Researchers are now testing alectinib in children with various cancers where ALK fusion protein is present.

Alectinib is a medicine taken by mouth in capsule form, after eating a meal. The hard capsules may be difficult for children to swallow. Thus, researchers are working on making a different type (formulation) that will be easier for children.

This study was done to compare the new liquid formulation of alectinib with the approved capsule formulation – to find out if the two formulations deliver the same amount of medicine in people.

What was the study medicine?

Alectinib is a medicine for treating cancer that has a certain protein present – called "ALK fusion protein". This study looked at 2 forms of the same medicine:

- **Alectinib oral capsules** – existing medicine
- **Alectinib oral liquid suspension** – this is a different form ("**formulation**") of the same medicine. It was compared to the existing formulation at the same dose.

Alectinib oral capsules are given to adults with a certain type of lung cancer – that has the ALK fusion protein present.

Alectinib oral liquid suspension - is a liquid formulation of the medicine that was studied here.

What did researchers want to find out?

The main questions that researchers wanted to answer were:

1. Was the same amount of medicine absorbed into the body from the two formulations?
2. Was there any difference in absorption if the medicine was taken with or without food?

What kind of study was this?

Several phrases describe different parts of the study design:

- **Randomized study**
  People were randomly assigned to a group that either got Form A of the medicine first and then Form B, or they got Form B of the medicine first and then Form A. Being randomized means it was decided by chance which group you got assigned to.

- **Open-label study**
  This study was open label which means that after you were randomly placed in a group, you knew what medicine you were getting.

- **Two-treatment study**
  There were two treatments in this study.

- **Two-period study**
  After taking the first form of the medicine that you were assigned to, you had to wait for at least 14 days before you could take the other form. This means the two forms of the medicine were taken several days apart.

- **Two-way crossover study**
  People who were assigned to take "Form A" took the medicine. Several days later, they "crossed over" and became the group that was given "Form B" of the medicine. The same happened in reverse to people in the other group.

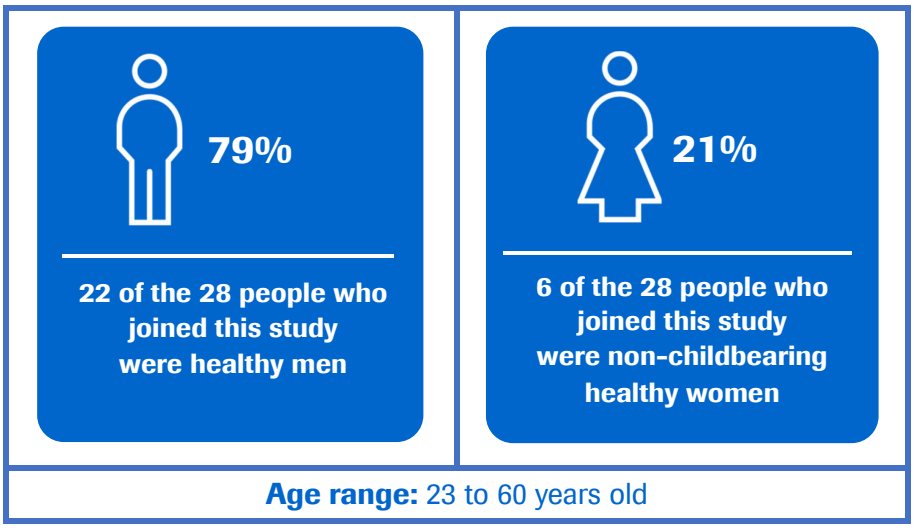
When and where did the study take place?

The study started in January 2021 and finished in March 2021. This summary was written after the study had ended.

The study took place at one study center in one country – the United Kingdom.

2. Who took part in this study?

Twenty-eight healthy people took part in this study.



People could take part in the study if:

- They were men and women between 18 to 60 years old.
- They had a certain height-weight ratio (BMI range 18 to 32 kg/m^2).
- They were in good health according to a doctor who asked questions and did medical tests.
- They tested negative for drugs and alcohol.
- Women were not pregnant, able to get pregnant, or breastfeeding.
- Men agreed to use methods to avoid getting their partners pregnant.

People could not take part in the study if:

- They had a history of certain health issues.
- Some types of allergies were not allowed as determined by the doctor.
- They had a history of drug or alcohol abuse, or consumed alcohol beyond a certain limit.
- They used certain medicine or products in the last 6 months – biologic therapies, tobacco, or nicotine products.
- They recently participated in another clinical trial.
- They were using or were going to use certain medicines – non-prescription products.
- They were not willing to avoid strenuous activity, sunlight, or tanning beds for 96 hours prior to checking in for the study.

3. What happened during the study?

Here are the two treatments given to people in this study:

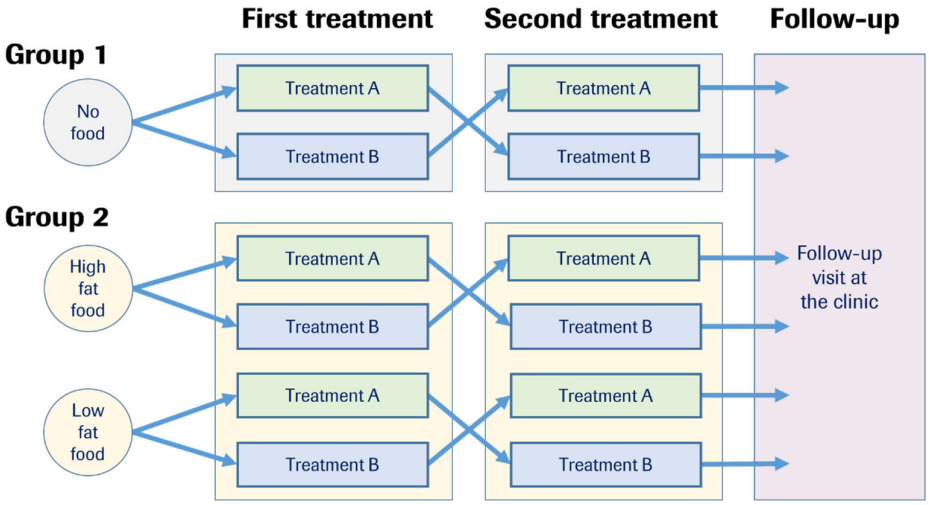
- **Treatment A**: 600 mg of alectinib capsules taken by mouth.
- **Treatment B**: 600 mg of alectinib taken by mouth as a suspension in water and mixed with an equal amount of apple juice.

Here are the groups that people were assigned to:

- **Group 1**: Fourteen people joined this group. They fasted for 10 hours (no food) before getting their treatment. They fasted for 4 hours (no food) after treatment. Water was restricted for 1 hour before and 2 hours after treatment. They were permitted to drink water without any restriction at all other times.
- **Group 2**: Fourteen people joined this group. They fasted for 10 hours (no food) overnight. They ate their breakfast in 15 minutes and got their treatment 15 minutes after that. Food was not allowed for 4 hours after treatment. Water was restricted for 1 hour before and 2 hours after treatment. They were permitted to drink water without any restriction at all other times.

People in the study were checked (screened) at some point during a 4 week period before the study started. If they qualified to participate in the study, here is what happened:

- One day before the first treatment, they checked into the study site and stayed there for a week. On treatment day, they got their assigned treatment. Researchers collected samples at several time points to find out how much of the medicine was present in the body.
- Everyone went home and returned to the clinic after at least 2 weeks had passed since their first treatment.
- One day before the second treatment, they checked into the study site and stayed there for a week, and went through the same routine as for the first treatment.
- People in the study returned to the clinic 10 to 12 days after the second treatment for a follow-up visit – to check their overall health.



4. What were the results of the study?

Question 1: Was the same amount of medicine absorbed into the body from the two formulations?

Researchers looked at blood samples collected from when participants got Treatment A (capsules) and compared that to when they got Treatment B (suspension).

They found that the **liquid suspension formulation delivered more exposure to the medicine in the body in comparison to** the same dose taken in **capsule formulation**.

Question 2: Was there any difference in absorption if the medicine was taken with or without food?

Researchers looked at blood samples collected from when people got their treatment after eating. They compared that to when they got treatment after fasting.

There was **more medicine absorbed** into the body when it was **taken with food**.

Absorptions was higher with a fatty meal in comparison to a low-fat meal.

This section only shows the key results from this study. You can find information about all other results on the websites at the end of this summary (see Section 8).

5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that happened during the study.

- They are described in this summary because the study doctor believes the side effects were related to the treatments in the study.
- Not all of the people in this study had all of the side effects.
- Side effects may be mild to very serious and can be different from person to person.
- It is important to be aware that the side effects reported here are from this single study. Therefore, the side effects shown here may be different from those seen in other studies, or those that appear on the medicine leaflet.
- Serious and common side effects are listed in the following sections.

Serious side effects

A side effect is considered “serious” if it is life-threatening, needs hospital care, or causes lasting problems.

During this study, there were no serious side effects.

There were no deaths on this study. Everyone on the study got two alectinib treatments – one in capsule form and another in suspension form.

Most common side effects

Three of the 28 people (11%) on this study had side effects not considered serious – but thought to be related to the treatments.

- One person had a headache - and felt sleepy and drowsy (somnolence).
- One person had a stomach ache (abdominal pain).
- One person felt sleepy and drowsy (somnolence).

Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see Section 8.

6. How has this study helped research?

The information presented here is from a single study of 28 healthy people. These results helped researchers learn more about alectinib and how it could be given to children with cancer.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

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7. Are there plans for other studies?

Several studies with alectinib are on-going at the time of writing this report.

8. Where can I find more information?

You can find more information about this study on the websites listed below:

https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-003891-42/results

https://forpatients.roche.com/en/trials/healthy-volunteers/a-study-to-find-out-if-people-get-the-same-amount-of-medicine--a.html

Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/About.html
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

Who organized and paid for this study?

This study was organized and paid for by Genentech, Inc., South San Francisco, CA, USA. Genentech is part of F. Hoffmann-La Roche Ltd., with headquarters in Basel, Switzerland.

Full title of the study and other identifying information

The full title of this study is:

"A randomized, open-label, two-treatment, two-part, study to explore the performance of alectinib extemporaneous suspension on alectinib capsule bioavailability in healthy subjects in fed and fasted conditions."

- The protocol number for this study is GP42776.
- The EudraCT number for this study is 2020-003891-42.